



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,427	09/30/2005	Andrew David Miller	CU-4022 RJS	6762
26530	7590	12/06/2006	EXAMINER	
LADAS & PARRY LLP 224 SOUTH MICHIGAN AVENUE SUITE 1600 CHICAGO, IL 60604			LAO, MARIALOUISA	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/518,427

Applicant(s)

MILLER ET AL.

Examiner

MLouisa Lao

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. This application contains claims directed to the following patentably distinct species: The species of a lipid compound.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

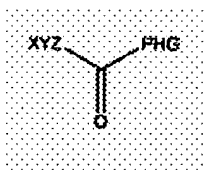
Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1621

The species of a lipid compound, *inter alia*, comprising at least one non-polar moiety and a polar moiety, are as recited in the corresponding claims below:

1- compound of claim 4



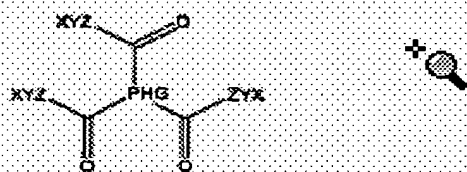
2- compound of claim 5 and 7, respectively

Claim 5. A lipid compound comprising at least one non-polar moiety and a polar moiety, wherein each or at least one non-polar moiety is of the formula X-Y-Z- wherein X is a hydrocarbyl chain, Y is selected from at least one of S, Se, SO<sub>2</sub>, SO, and O, and Z is an optional hydrocarbyl group, wherein the polar moiety is of the formula

-[C(O)]<sub>m</sub>PHG

Wherein PHG is a polar head group, and wherein m is the number of non-polar moieties.

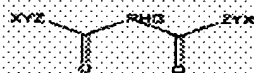
7. (original) A compound according to claim 5 wherein the compound is of the formula



wherein each X, Y and Z is selected independently of each other.

3- compound of claim 6

6. (original) A compound according to claim 3 wherein the compound is of the formula



wherein each X, Y and Z is selected independently of each other.

4- compound of claim 24

A compound according to claim 1 wherein Y-Z together represent the group [Y<sub>1</sub>-CH<sub>2</sub>]<sub>n</sub>

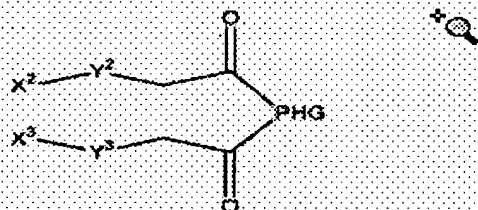
wherein y<sub>1</sub> is selected from S, Se, SO<sub>2</sub>, SO, O, OH<sub>2</sub>, wherein when y<sub>1</sub> is OH<sub>2</sub>, the

Art Unit: 1621

chain X-Y-Z contains an even number of atoms, and wherein n is an integer from 1 to 20

5- compound of claims 30 and 34-35

30. (original) A compound according to claim 1 wherein the compound is of the formula



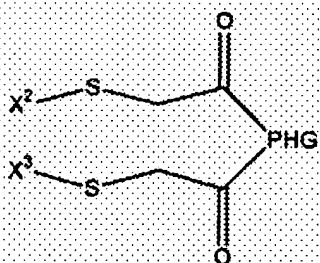
wherein Y<sup>2</sup> and Y<sup>3</sup> are independently S or Se, and X<sup>2</sup> and X<sup>3</sup> are independently selected from unsubstituted C<sub>10</sub>-C<sub>18</sub> alkyl, unsubstituted C<sub>10</sub>-C<sub>18</sub> alkenyl and unsubstituted C<sub>10</sub>-C<sub>18</sub> alkynyl.

34. (original) A compound according to claim 30, 31, 32 or 33 wherein the polar head group is derived from the polar head group of a phospholipid.

35. (original) A compound according to claim 34 wherein the phospholipid is a phosphatidylcholine (PC) or a phosphatidylethanolamine (PE).

6- compound of claims 31 and 34-35

31. (original) A compound according to claim 1 wherein the compound is of the formula



X<sup>2</sup> and X<sup>3</sup> are independently selected from unsubstituted C<sub>10</sub>-C<sub>18</sub> alkyl, unsubstituted C<sub>10</sub>-C<sub>18</sub> alkenyl and unsubstituted C<sub>10</sub>-C<sub>18</sub> alkynyl.

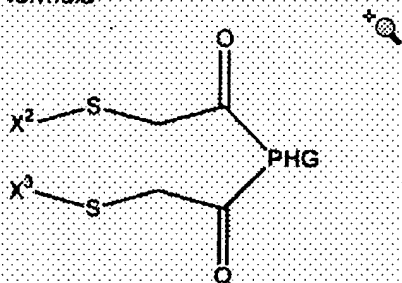
34. (original) A compound according to claim 30, 31, 32 or 33 wherein the polar head group is derived from the polar head group of a phospholipid.

35. (original) A compound according to claim 34 wherein the phospholipid is a phosphatidylcholine (PC) or a phosphatidylethanolamine (PE).

Art Unit: 1621

## 7- compound of claims 32 and 34-35

32. (original) A compound according to claim 1 wherein the compound is of the formula



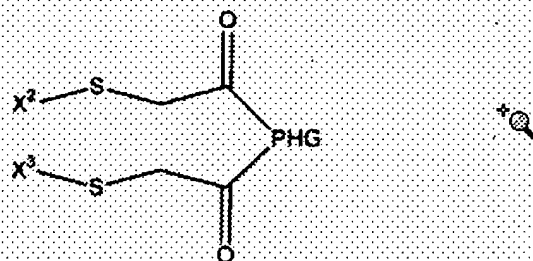
$X^2$  and  $X^3$  are independently selected from unsubstituted  $C_{14}$  alkyl, unsubstituted  $C_{14}$  alkenyl and unsubstituted  $C_{14}$  alkynyl.

34. (original) A compound according to claim 30, 31, 32 or 33 wherein the polar head group is derived from the polar head group of a phospholipid.

35. (original) A compound according to claim 34 wherein the phospholipid is a phosphatidylcholine (PC) or a phosphatidylethanolamine (PE).

## 8- compound of claims 33 and 34-35

33. (original) A compound according to claim 1 wherein the compound is of the formula



$X^2$  and  $X^3$  are independently selected from  $CH_3(CH_2)_{13}$ ,  $CH_3(CH_2)_6CH=CH(CH_2)_5$ , and  $CH_3CH_2C\equiv C(CH_2)_{10}$ .

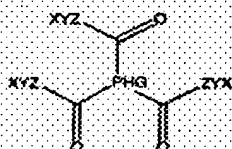
34. (original) A compound according to claim 30, 31, 32 or 33 wherein the polar head group is derived from the polar head group of a phospholipid.

35. (original) A compound according to claim 34 wherein the phospholipid is a phosphatidylcholine (PC) or a phosphatidylethanolamine (PE).

Art Unit: 1621

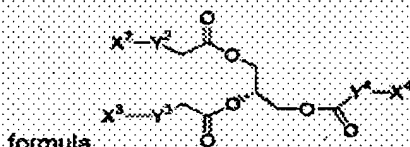
## 9- compound of claims 36-38

36. (original) A compound according to claim 1 wherein the compound is of the formula



wherein each W, X, Y and Z is selected independently of each other.

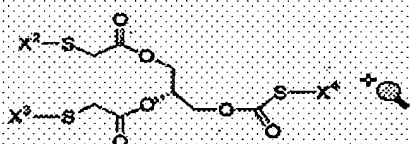
37. (original) A compound according to claim 36 wherein the compound is of the formula



formula

wherein Y², Y³ and Y⁴ are independently S or Se, and X², X³ and X⁴ are independently selected from C<sub>10</sub>-C<sub>18</sub> alkyl, C<sub>10</sub>-C<sub>18</sub> alkenyl and C<sub>10</sub>-C<sub>18</sub> alkynyl.

38. (original) A compound according to claim 36 wherein the compound is of the formula



wherein X², X³ and X⁴ are independently selected from C<sub>10</sub>-C<sub>18</sub> alkyl, C<sub>10</sub>-C<sub>18</sub> alkenyl and C<sub>10</sub>-C<sub>18</sub> alkynyl.

B. This application contains claims directed to the following patentably distinct species: the species of a pharmaceutical composition.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Art Unit: 1621

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species of a pharmaceutical composition, are as recited in the corresponding claims below and are not repeated verbatim so as not to obfuscate that which the applicants intended:

- 1- in claim 40
- 2- in claim 57
- 3- in claim 58
- 4- in claim 59
- 5- in claim 60

C. This application contains claims directed to the following patentably distinct species: the species of a method and the plurality of diseases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The applicant is further required to elect a single disclosed disease.



Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species of a method, are as recited in the corresponding claims below:

- 1- in claim 45
- 2- in claim 46
- 3- in claim 47
- 4- in claim 48
- 5- in claim 49
- 6- in claim 50
- 7- in claim 51
- 8- in claim 52
- 9- in claim 53
- 10- in claim 54
- 11- in claim 55
- 12- in claim 56

Art Unit: 1621

Applicant is required, in reply to this action, to elect a single disclosed species of each group (A, B, C) and one disclosed disease for group C, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

3. The claims are deemed to correspond to the species as listed in the manner, presented above.

The following corresponding claim(s) are generic:

For A- 1, 8, 12, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23

For B- 39

For C- none

Art Unit: 1621

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

for A – the substituents on the core structure render the ensuing structures to invariably exhibit different chemical properties;

for B – the compositions from the using the different compounds will likewise have distinct features; and,

for C- the methods recited purport to different modes of purported use.

#### ***Information Disclosure Statement***

5. The information disclosure statement filed on August 28, 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because Foreign Patents EP0250994 and PCT3014073 are in non-English Format and Foreign Patent EP0447553 and Other Documents' Horiike et al., Bestmann et al, Bartnik et al. and Kuni, Jun et al. pertain to subject matters irrelevant to the instant application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Art Unit: 1621

6. A telephone call was not made to applicants' agent to request an oral election to the above restriction requirement due to the complexity of the art. MPEP §812.01

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1621

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on 8:30am to 5:30pm Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

---

mll111606

THURMAN K. PAGE  
SUPERVISOR, PATENT EXAMINER  
TECHNOLOGY CENTER 1600